Notice of Allowability	Application No.	Applicant(s)	
	09/857,144	DENIS ET AL.	
	Examiner	Art Unit	
	LoAn H. Thanh	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 05/06/04*.

2. ☒ The allowed claim(s) is/are *14-34*.

3. ☒ The drawings filed on *08 February 2002* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

LoAn H. Thanh
Primary Examiner
Art Unit: 3763

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Klifton Kime on 06/24/04 and 06/25/04.

Please rewrite claim 14 as follows:

A safety assembly for a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position, the body of the syringe having a proximal end provided with a flange, the assembly further comprising:

a tubular sheath in which the body of the syringe is designed to be housed in axially displaceable manner between an active position in which the needle projects through a distal end of the sheath and a protection position in which the needle is retracted inside the sheath;

resilient return means for urging the body towards its protection position;

locking means for preventing the body from moving relative to the sheath in the active position by opposing the resilient force of the return means;

release means for releasing said locking means when the plunger is in its end-of-injection position;

the locking means comprising two diametrically opposite lugs formed in a wall of the tubular sheath, each lug having a free end provided with a retractable catch;

a cap mounted to slide axially on the sheath between two positions and having a proximal end with a hole for receiving the plunger;

snap-fastening means comprising an internal catch for securing the cap to the tubular body, so that due to retraction of the retractable catches, the cap is moved by resilient return means; and

two complementary shoulders acting as abutments, one on the cap, the other one on the tubular sheath, to limit the stroke of the cap once the locking means have been released, in opposition to the resilient force of the return means.

In claim 15, line 1, "An " has been deleted and replaced with ---The---.

In claim 16, line 1, "An " has been deleted and replaced with ---The---.

In claim 17, line 1, "An " has been deleted and replaced with ---The---.

In claim 18, line 1, "An " has been deleted and replaced with ---The---.

In claim 19, line 1, "An " has been deleted and replaced with ---The---.

In claim 20, line 1, "An " has been deleted and replaced with ---The---.

In claim 21, line 1, "An " has been deleted and replaced with ---The---.

Please rewrite claim 22 as follows: The safety assembly according to claim 14 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a

needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 23 as follows: The safety assembly according to claim 15 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 24 as follows: The safety assembly according to claim 16 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 25 as follows: The safety assembly according to claim 17 further comprising an injection device injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 26 as follows: The safety assembly according to claim 18 further comprising an injection device injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 27 as follows: The safety assembly according to claim 19 further comprising an injection device injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 28 as follows: The safety assembly according to claim 20 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 29 as follows: The safety assembly according to claim 21 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 30 as follows: A safety assembly for a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position, the body of the syringe having a proximal end provided with a flange, the assembly further comprising:

a tubular sheath in which the body of the syringe is designed to be housed in axially displaceable manner between an active position in which the needle projects through a distal end of the sheath and a protection position in which the needle is retracted inside the sheath;

resilient return means for urging the body towards its protection position;

locking means for preventing the body from moving relative to the sheath in the active position by opposing the resilient force of the return means, said locking means being released by release means when the plunger is in its end-of-injection position;

the locking means comprising two diametrically opposite lugs formed in a wall of the tubular sheath, each lug having a free end provided with a retractable catch;

a cap mounted to slide axially on the sheath between two positions and having a proximal end with a hole for receiving the plunger;

an internal catch for snap-fastening the flange of the tubular body to the cap, so that due to retraction of the retractable catches, the cap is moved by resilient return means; and

two complementary shoulders acting as abutments, one on the cap, the other one on the tubular sheath, to limit the stroke of the cap once the locking means have been released, in opposition to the resilient force of the return means;

wherein the sheath and the cap are generally in the form of bodies of revolution and have complementary means for preventing relative rotation between each other; and

wherein the complementary means for preventing relative rotation of the sheath and the cap comprise at least one longitudinal groove formed in the cap and co-operating with a corresponding finger secured to the sheath.

Please rewrite claim 31 as follows: A safety assembly for a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position, the body of the syringe having a proximal end provided with a flange, the assembly further comprising:

a tubular sheath in which the body of the syringe is designed to be housed in axially displaceable manner between an active position in which the needle projects through a distal end of the sheath and a protection position in which the needle is retracted inside the sheath;

resilient return means for urging the body towards its protection position;

locking means for preventing the body from moving relative to the sheath in the active position by opposing the resilient force of the return means, said locking means being released by release means when the plunger is in its end-of-injection position;

the locking means comprising two diametrically opposite lugs formed in a wall of the tubular sheath, each lug having a free end provided with a retractable catch;

a cap mounted to slide axially on the sheath between two positions and having a proximal end with a hole for receiving the plunger;

an internal catch for snap-fastening the flange of the tubular body to the cap, so that due to retraction of the retractable catches, the cap is moved by resilient return means; and

two complementary shoulders acting as abutments, one on the cap, the other one on the tubular sheath, to limit the stroke of the cap once the locking means have been released, in opposition to the resilient force of the return means;

wherein the sheath and the cap are generally in the form of bodies of revolution and have complementary means for preventing relative rotation between each other; and

wherein the complementary means for preventing relative rotation of the sheath and the cap comprise at least one axial slot formed in the cap and co-operating with a fin.

Please rewrite claim 32 as follows: The safety assembly according to claim 30 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 33 as follows: The safety assembly according to claim 31 further comprising an injection device comprising a prefilled syringe for injecting liquid, the syringe comprising a tubular body forming a reservoir for the liquid, carrying a needle for injecting the liquid, and having a plunger mounted in the body to be movable between a ready position and an end-of-injection position.

Please rewrite claim 34 as follows: An assembly according to claim 14, wherein the release means comprises a ramp on the cap.

Claim 14 is generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 15-17 and 23-25, directed to the species of figures 1-4 are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim. In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The following is an examiner's statement of reasons for allowance: Jansen et al. does not teach or render obvious a safety assembly for a syringe comprising a tubular sheath which extends and retracts to protect the needle of the syringe, a spring, a cap and further in combination with a locking means which is released by a release means and a snap fastening means which secures the cap to the tubular sheath.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LoAn H. Thanh
Primary Examiner
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